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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,106	04/19/2004	Gopi M. Venkatesh	EURA-008/00US 307853-2228	1448

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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
02/19/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/827,106	VENKATESH ET AL.	
	Examiner	Art Unit	
	JAGADISHWAR R. SAMALA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendments and Remarks filed on 10/16/2009.

- Claims 1 and 11 have been amended.
- Claims 1-15 are pending in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gowan (US 5,876,759)in view of Ohta Motohiro et al (EP 914818 A1) and Guo et al (US 2004/0068000 A1) **are maintained** for the reason of record in the previous office action filed on 04/16/2009.

Applicant's arguments filed on 10/16/2009 have been fully considered but they are not persuasive.

Applicant argues that Gowan fails to teach or suggest the granulated, wet milled and microencapsulated particles comprising a drug and a binder.

This argument is not persuasive because claims are product-by-process claims, which are not limited to the manipulations of the recited steps, but only the structure implied by the steps. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even thought the prior product was made by a different process. *See In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 966 (Fed. Cir. 1985). Here, no structural or functional differences are apparent from the method the pharmaceutical or granulated pharmaceuticals are formed because the method used in the prior art does not use wet milled or additional coating for microencapsulating particles. With regards to claims, the resulting product is also granulated pharmaceutical particles coated with binders such as cellulosic derivatives, or ethyl cellulose/HPC polymer which appears to be the same as when made by wet milled method.

Applicant argues that Gowan teaches the disintegration can be provided by a compressible carbohydrate alone, rather than the claimed rapid release granules comprising the combination of <30 micron sugar alcohol or saccharide particles and a disintegrant.

Applicant is right that Gowan teaches water disintegratable, compressible carbohydrates include mannitol, sorbitol or mixtures and therefore an obviousness rejection is made. Guo reference teaches an oral dosage form comprising active ingredient coated with disintegrant such as crospovidone, hydroxypropyl cellulose.

Applicant argues that Guo fails to disclose: (a) individually taste-masked particles prepared by wet milling a granulate comprising the combination of a drug and binder; and (b) rapidly dispersing granules comprising the combination of <30 micro sugar alcohol or a saccharide particles and a disintegrant and the dosage forms of Guo are intended to be swallowed whole, without disintegrating in the oral cavity of the patient.

This argument is not persuasive because this reference is combined for its teachings of knowledge in the art of solid core formulation (tablet) comprising an active ingredient, a disintegrant, binder, filler and the coating layer which covers or conceals the core tablet. Further, in one embodiment, the compression coating formulation is prepared by blending 127.5 mg lactose with 120 mg microcrystalline cellulose, and then mixing with 2.5 mg magnesium stearate. The obtained powder is then compression coated around the tablet core comprising active ingredient, disintegrant (0034-0036). This process would obviously provide an dosage form of the unpleasant taste associated with oral administration, wherein the active drug substance is covered or coated by pleasant non-interacting materials, makes the formulations easier to handle and are attained without any significant loss in the bioavailability of the active compound which remains similar to film coated tablets.

Applicant argues that Ohta does not teach the microencapsulated drug particles, or otherwise taste-masked, do not include a polymeric binder, and are not prepared with a wet milling process step.

This argument is not persuasive because this reference is combined for its teachings of knowledge in the art of tablet comprising sugar alcohol or saccharide having an average particle diameter of not more than 30 microns, an active ingredient, and a disintegrant such as crosspovidone, crosscarmellose sodium. Further, Ohta teaches that the tablet can be obtained by compressing and tableting after granulating a mixed powdered component comprising sugar alcohol or saccharide having an average particle diameter of not more than 30 microns ground by means of a hammer mill or a jet mill or the like, an active ingredient and a disintegrant (0017). A wet granulation method using purified water, ethanol or the like can be preferably used.

Applicant also argues that one skilled in the art would not have been motivated to incorporate the sugar alcohol or saccharide particles of Ohta into the tablets of Gowan for the simple reason that in the tablets of Gowan the drug already is coated with taste-masking polymer, which are released from the dosage form with no objectable taste.

This argument is not persuasive because, Applicants use the transition term "comprising." This term is inclusive or open- ended and does not exclude additional, unrecited elements or process steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004). See MPEP 2111.03. As such, in addition to the particular ingredients being claimed, the claims are open to any other ingredient. The prior art references teach the same ingredients being claimed, in rapidly

disintegrating tablet comprising active agent, sugar alcohol or saccharide and a disintegrant, as explained in the obviousness rejection. As such, examiner respectfully submits that the prior art renders the instant claims obvious, as they are currently constructed.

Conclusion

No claims are allowed at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr